

107TH CONGRESS  
1ST SESSION

# S. 1341

To amend the Internal Revenue Code of 1986 to expand human clinical trials qualifying for the orphan drug credit, and for other purposes.

---

IN THE SENATE OF THE UNITED STATES

AUGUST 2, 2001

Mr. HATCH (for himself, Mr. KENNEDY, and Mr. JEFFORDS) introduced the following bill; which was read twice and referred to the Committee on Finance

---

## A BILL

To amend the Internal Revenue Code of 1986 to expand human clinical trials qualifying for the orphan drug credit, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. EXPANDED HUMAN CLINICAL TRIALS QUALI-**  
4 **FYING FOR ORPHAN DRUG CREDIT.**

5 (a) IN GENERAL.—Subclause (I) of section  
6 45C(b)(2)(A)(ii) of the Internal Revenue Code of 1986 is  
7 amended to read as follows:

8 “(I) after the date that the appli-  
9 cation is filed for designation under  
10 such section 526, and”.

1 (b) CONFORMING AMENDMENT.—Clause (i) of sec-  
 2 tion 45C(b)(2)(A) of the Internal Revenue Code of 1986  
 3 is amended by inserting “which is” before “being” and  
 4 by inserting before the comma at the end “and which is  
 5 designated under section 526 of such Act”.

6 (c) EFFECTIVE DATE.—The amendments made by  
 7 this section shall apply to amounts paid or incurred after  
 8 December 31, 2001.

9 **SEC. 2. PUBLICATION OF FILING AND APPROVAL OF RE-**  
 10 **QUESTS FOR DESIGNATION OF DRUGS FOR**  
 11 **RARE DISEASES OR CONDITIONS.**

12 Subsection (c) of section 526 of the Federal Food,  
 13 Drug, and Cosmetic Act (21 U.S.C. 360bb) is amended  
 14 to read as follows:

15 “(c) Not less than monthly, the Secretary shall pub-  
 16 lish in the Federal Register, and otherwise make available  
 17 to the public, notice of requests for designation of a drug  
 18 under subsection (a) and approvals of such requests. Such  
 19 notice shall include—

20 “(1) the name and address of the manufacturer  
 21 and the sponsor;

22 “(2) the date of the request for designation or  
 23 of the approval of such request;

24 “(3) the nonproprietary name of the drug and  
 25 the name of the drug under which an application is

1        filed under section 505(b) or section 351 of the Pub-  
2        lic Health Service Act;

3            “(4) the rare disease or condition for which the  
4        designation is requested or approved; and

5            “(5) the proposed indication for use of the  
6        product.”.

○